

Appl. No. : **10/691,224**
Filed : **October 22, 2003**

REMARKS

Claim1 has been amended to more clearly claim the invention. Claim 2 has been cancelled. Claims 3 and 4 have been amended to correct minor informalities and dependencies. Support for the amendment to Claim 1 can be found in the Specification and claims as filed, for example, Claim 2, and Figures 20, 25, 27, and 28. The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

As requested by the Office Action, the Priority information has been amended to reflect the issued patent and the Summary of the Invention has been amended to reflect the elected claim set. A copy of the IDS of January 25, 2004 is enclosed containing the patent GB 1,335,290 which was mistakenly left out of the IDS.

Claim objections

In the Office Action, the following Claims were objected to: Claim 5 for not including the word “one”, Claim 2 for reciting “the cylinder” with no antecedent basis, and Claims 3 for reciting “the inner wall surface” and “the syringe barrel side” with no antecedent basis. Claim 2 was cancelled rendering the rejection moot. Claims 3 and 5 have been amended to remove these objections.

Rejection under 35 U.S.C. §102(b)

Claim 1 stands rejected as anticipated by Ambruster et al (USPN 5,322,511) (hereinafter “Armbruster”). The Office Action states that Armbruster discloses an injector with a syringe barrel (80) having a flange (92) and a guide (94,96,96’ or 94,98, 98’) in Figures 11-12 and that Figure 10 shows a groove for the insertion of the flange and the flange inserted in the groove. Figure 16 shows the guide engaging a portion (74) of the cylinder holder. The Examiner believes that this “lock and key” mechanism restricts the mounting direction of the syringe barrel.

Claim 1 as amended is directed to a syringe barrel adapted to be mounted on a cylinder holder into a flange insertion groove. The syringe barrel includes a flange adapted to be inserted

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in the flange insertion groove, and a guide which engages the cylinder holder and restricts the mounting direction of the syringe barrel. Claim 1 has also been amended to include the limitations of Claim 2, that the guide is a projection, and to recite that “the syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves.”

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

The guide of Armbruster on the flange is a concavity which fits into a projection in the flange insertion groove of the cylinder holder. In contrast, the guide of Claim 1 is a projection. Thus, the concave guide of Armbruster does not anticipate the projection guide as presently claimed. In addition, Applicants would like to note that the Claim has been amended to recite the limitations of Claim 2 which the Office Action did not state was anticipated by Armbruster. Thus, Applicants respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. §102(e)

Claims 1-3 stand rejected as anticipated by Reilly et al. (US Pub 2002/0165491) (hereinafter “Reilly”) because the Office Action asserts that Reilly discloses a syringe and injector system with a syringe barrel (100) including a flange (threading 130) and a guide (140) in Figure 2A. The Office Action states that the term flange is understood to be “a rib or rim for strength, for guiding, or for attachment to another object”. In view of this, the Office Action asserts that that the threading (130) is a rim of the syringe barrel and is used for attachment to the injector which makes it a flange.

However, Claim 1 has been amended to include the limitations of Claim 2, that the guide is a projection, and to further include the language “the syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves.”

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As shown in Figure 2A, the threading 130 of Reilly is not a flange by the definition of the word (a projecting rim or edge; Oxford American Dictionary). The threading is, in fact, a threading to be screwed onto the injector. In addition, the mounting direction is not taught or suggested by Reilly and the syringe of Reilly could not be mounted “from the direction parallel to the insertion grooves.” Thus, Reilly does not anticipate the invention because Reilly does not teach a guide which is a projection on the flange or that can be mounted from a direction parallel to the insertion grooves.”.

Rejection under 35 U.S.C. §103(a)

Claim 4 stands rejected as unpatentable over Reilly in view of Fago et al (USPN 6,569,127) (hereinafter “Fago”. The Office Action asserts that Reilly meets the claim limitations for claims 1 and 2, but fails to include the cylinder holder having two clamps. However, the Examiner believes that Fago discloses a cylinder holder having two clamps (90a and 90b).

The law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure (*In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1440 (Fed. Cir. 1991)).

As mentioned above in the 102(e) rejection, Reilly does not disclose a flange or that “the syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves.” Fago does not provide the missing claim elements since Fago teaches a syringe that is mounted on the cylinder holder similarly to that in Reilly requiring a twisting motion. Fago does not provide the missing claim elements because it does not teach or suggest that “the syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves” and, therefore, the combination does not render the claimed invention obvious.

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Double Patenting Rejections

Claim 1 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,676,635 (hereinafter '635) and Claim 4 of copending Application No.10/211,099 (hereinafter "the '099 application").

1. The '635 patent claims a syringe barrel that can be mounted on a cylinder holder comprising: a concave portion which is formed on the flange that can be engaged with a positioning mechanism installed in the cylinder holder (an example of the positioning mechanism is a latch pushed by a coil spring or a blade spring having a pawl).

However, Claim 1 as amended is directed to a syringe barrel including a flange adapted to be inserted in the flange insertion groove, and a guide, a projection, which engages the cylinder holder and restricts the mounting direction of the syringe barrel. Claim 1 has also been amended to specify that the guide is a projection and to recite that "the syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves."

The Claims of '635 do not provisionally render the claimed invention obvious because they claim a concavity on the syringe, while the claimed invention is a projection. Thus, Applicants respectfully request withdrawal of the rejection.

2. The '099 application claims a syringe barrel having a flange, comprising a guide projection on a front surface of the flange. Applicants would like the Examiner to note that Application No. 10/211,099 has been abandoned and that Application No. 10/781,124 is now pending as a Divisional application. In 10/781,124, the claims are directed to a solution injection system with a syringe having an arcuate guide projection configured to engage with the guide groove of the barrel holder when the syringe barrel is inserted into the barrel holder. Thus, the guide projection does not "restrict the mounting direction of the syringe barrel." See also Figure 6b. In fact, the syringe groove is made so as to accommodate the guide projection on the surface of the flange, whereas, as stated in Claim 1, the guide projection of the present invention is not fitted in the flange insertion groove. Thus, Application number 10/211,099 does not provisionally render the claimed invention obvious.

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Conclusion

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: July 11, 2005

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